## REMARKS

### I. Status of the Application

This is a response to the Office Action mailed on March 1, 2010 (the "Office Action"). Claims 1, 3-7, 9-11, 13-18, 20-29 and 31-40 are now pending. Claims 1, 3-7, 9-11, 13-18, 20-29 and 31-40 are rejected. By way of this response, Claims 1, 13, 18 and 20 have been amended, Claims 3, 6 and 24 has been cancelled and Claims 41-43 are added. No new matter is presented by way of the amendments. Cancellation of any subject matter herein does not constitute an admission that the subject matter is unpatentable for any reason and Applicants reserve the right to file claims directed to cancelled subject matter in this or a related application. Support for the amended and new claims can be found throughout the claims and specification as filed including, *inter alia*, in the claims as originally filed; page 9, lines 13-17; page 27, lines 7-22; and Example 1, page 38, lines 5-9 and page 39, lines 19-21.

Entry and consideration of the amendments to the claims is respectfully requested. Applicants submit that the amendments submitted herewith place all of the pending claims in condition for allowance.

### II. Rejections Under 35 U.S.C. § 103

**A.** Claims 1, 3-7, 9-11, 13-18, 20-21, 23-29 and 31-40 were rejected under 35 U.S.C. § 103(a), as being unpatentable over Palmer et al. (Clinical Lung Cancer 2001; 3 (1): 49-57), in view of Sugiura (Clinical Cancer Research 1999; Vol. 3: 47-50). The Office asserts:

> Palmer et al. teach a method of treating an individual with non-small lung cancer stage IIIB or IV comprising: (a) selecting for treatment an individual who has small cell lung cancer stage IIIB or IV; (b) administering a priming dose of cyclophosphamide; and (c) administering to that individual an amount of a formulation comprising a liposome comprising a 20 or 200 μg of a MUC-1 lipopolypeptide referred to as BLP25, 100 mg of Lipid A and 20 mg/mL liposomal lipids [...] *Office Action, pages 2-3.*

The Office, however, admits that Palmer et al. does not specifically teach patients having stage IIIB locoregional (without malignant pleural effusion) NSCLC and administering said formulation to said patient. To overcome the deficiencies of Palmer, the Office cites Sugiura et al. for its disclosure on

the survival times of patients with stage IIIB without effusion, stage IIIB with effusion and stage IV NSCLC.

Given these teachings, the Office alleges:

> It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teaches of the reference so as to modify the method taught by Palmer et al. to select patients suffering from stage IIIB locoregional (without malignant pleural effusion) in view of the teachings of Sugiura et al. *Office Action, page 4.*

Applicants respectfully traverse this rejection, but in the interest of expediting allowance of the claims, amend the claims to recite selecting an individual with NSCLC stage IIIb locoregional, without malignant pleural effusion, and "whose cancer has responded to treatment following completion of a first line standard chemotherapy and/or radiotherapy". Applicants submit that neither Palmer nor Sugiura describe or suggest patient selection wherein the patient's cancer has responded to treatment following completion of a first line standard chemotherapy and/or radiotherapy for the administration of a MUC-1 based formulation.

Moreover, Applicants submit that Palmer and its accompanying commentary (Schiffman and Disis, Clinical Lung Cancer 2001; 3 (1): 58) (hereinafter, "Palmer Commentary"), actually teach away from the instant claims. As the Office is aware, "[a] prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the invention." (MPEP §2141, *citing W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (emphasis in original)). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference..." (*In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1130 (Fed. Cir. 1994) (emphasis added)). Indeed, "[a] reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." ((*Id.*) (emphasis added)).

The Palmer Commentary states:

> [T]here is evidence that cytotoxic chemotherapy in itself may result in delayed T-cell regeneration and T-cell subset imbalance. For example, numerically, $CD4^+$ T cells are 50% of normal levels for as long as

12-14 months after chemotherapy. Moreover, when stimulated by mitogens, there is an increased susceptibility for T cells from patients previously treated with chemotherapy to apoptose as compared with normal donors. *Palmer Commentary, col. 3, para. 2.*

Thus, from the Palmer Commentary, one of ordinary skill in the art would be discouraged from selecting patients with previous treatment with chemo- or radiotherapy for administration of a subsequent MUC-1 based formulation for an immune response as such a selection would be unlikely to be productive. As the Palmer Commentary has noted, such prior treatment will result in delayed levels and regeneration of T cells as well as increased susceptibility of the T cells to apoptose when stimulated. In this respect, in view of the prior art, a patient that had a first-line therapy of chemo- or radiotherapy would appear to be a poor selection for administration of a MUC-1 based formulation.

Accordingly, in light of the amendments and arguments submitted herein, Applicants respectfully solicit withdrawal of this rejection.

**B.** Claim 22 under 35 U.S.C. § 103(a), was also rejected as being unpatentable over Palmer et al. (Clinical Lung Cancer 2001; 3 (1): 49-57), in view of Sugiura (Clinical Cancer Research 1999; Vol. 3: 47-50) as applied to Claims 1, 3-7, 9-11, 13-18, 20-21, 23-29 and 31-40, in further view of Palmer et al. (Annals of Oncology 2000; 11 (supplement 4): page 42, Abstract 179PD), hereinafter referred to as "Palmer 2".

Applicants respectfully traverse this rejection, but in the interest of expediting allowance of the claims, amend the independent claim on which Claim 22 is dependent upon to recite selecting an individual with NSCLC stage IIIb locoregional, without malignant pleural effusion, and "whose cancer has responded to treatment following completion of a first line standard chemotherapy and/or radiotherapy". As noted *supra*, neither Palmer nor Sugiura describe or suggest this patient selection. Further, Palmer 2 also fails to describe selecting for patients whose cancer has responded to treatment following completion of a first line standard chemotherapy and/or radiotherapy.

Accordingly, in light of the amendments submitted herein and for the same reasons set forth above, Applicants respectfully solicit withdrawal of this rejection.

**C.** Claim 6 under 35 U.S.C. § 103(a), was also rejected as allegedly being unpatentable over Palmer et al. (Clinical Lung Cancer 2001; 3 (1): 49-57), in view of Sugiura (Clinical Cancer Research 1999; Vol. 3: 47-50) as applied to Claims 1, 3-7, 9-11, 13-18, 20-21, 23-29 and 31-40, in further view of Morse et al. (Current Opinion in Molecular Therapeutics 2001; 3: 102-105).

Without admitting or conceding the appropriateness of this rejection and in order to expedite prosecution, Applicants have cancelled Claim 6, thereby making this rejection moot.

## CONCLUSION

Applicants submit that this response fully addresses the Office Action mailed March 3, 2010. Applicants believe that for the reasons set forth herein the pending claims are in condition for allowance and early and favorable consideration is respectfully requested. Further, none of Applicants' amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

Applicants also respectfully request an interview on the pending claims prior to issuance of a subsequent Office Action and will contact the Examiner for scheduling one.

Should the Examiner have any questions or concerns, the Examiner is encouraged to contact the undersigned attorney at (858) 350-2306.

Respectfully submitted,

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